CORE DIAGNOSTICS

[redacted]

Urgent Field Safety Notice

Urgent Product Correction

Immediate Action Required

Date Issued June 14, 2024

Product

Product Description	List Number	Serial Number	UDI
Alinity hq Analyzer	09P68-01	See Attachment 1	See Attachment 1

Explanation

Abbott has identified the following issues when using Alinity hq Analyzer software version 5.6 and below which will be corrected in software version 5.8.

Issue 1:
When processing a CBC+DIFF sample that immediately follows a CBC+DIFF+RETIC sample, diluent may backflow into the RBC dilution cup. This may result in falsely low Red Blood Cell (RBC) results and consequently falsely high Mean Cell Hemoglobin Concentration (MCHC), falsely high Mean Cell Hemoglobin (MCH), and falsely low Hematocrit (HCT).

Issue 2:
An overestimation of the basophil (BASO) count may occur on some samples when cell events are incorrectly counted as BASO during sample analysis. This may result in falsely increased BASO counts and %B (%BASO).

Alinity hq software version 5.8 is scheduled to be released in June 2024 and will be available as Abbott receives regulatory approval to distribute the updated software in your country. Once the country-specific regulatory approvals are obtained, your Abbott representative will be scheduling a mandatory upgrade of your Alinity hq Analyzer to install software version 5.8.

Impact on Patient Results

There is potential for incorrect results.

Necessary Actions to be Taken by Customer

- Issue 1:

  Continue to follow the Alinity h-series Operations Manual to verify flagged results.

  In addition, you must select one of the two options below depending on your laboratory workflow:

  Option 1: Batch your CBC+DIFF+RETIC samples on an analyzer. Ensure a Background cycle is run prior to processing the next CBC+DIFF sample on that analyzer.

  OR

  Option 2: The MCHC for the laboratories are typically set between 31 – 36 g/dL. In the event your patient sample flags MCHC results greater than the reference range in your lab, rerun the sample and ensure the rerun does not immediately follow a CBC+DIFF+RETIC sample.

- Issue 2:

  The %B high limit is typically set by the Laboratory between 2 – 5%. In the event your patient sample %B results are greater than the laboratory established high limit, follow the guidelines of your laboratory to rerun the sample or perform a manual slide review. Continue to follow the Alinity h-series Operations Manual to verify flagged results.

- Complete and return the Customer Reply Form.
- If you have forwarded the product listed above to other laboratories, please inform them of this Product Correction and provide to them a copy of this letter.
- Please retain this letter for your laboratory records.

Contact Information

If you or any of the health care providers you serve have questions regarding this information, please contact your local area Customer Service.

If you have experienced any patient or user injury associated with this Field Action, please immediately report the event to your local area Customer Service.